

REMARKS

Claims 1-5 and 10 are currently pending. Applicants reserve the right to file a continuation or divisional application claiming the subject matter of the cancelled or withdrawn claims which continuation or divisional application claims priority to the present application. No new matter is being hereby introduced.

Applicants acknowledge with thanks the withdrawal of the Examiner's objections to claim 5; to claims 1 and 2 under 35 U.S.C. §112, first paragraph, and to claims 1 and 5 under 35 U.S.C. §102 and 35 U.S.C. §103.

Amendments to the Claims

Claim 1 has been amended to substitute the transition phrase "consisting essentially of" with "consisting of." Claim 1 has also been amended to substitute the phrase "capital letters indicated D-amino acids" with "capital letters indicate D-amino acids."

Claim 2 has been amended to indicate a variant sequence and corresponding SEQ ID Nos and delete reference to the 88% homology. Support may be found throughout the instant specification, for example, in Table 1 and at page 15, lines 1 to 6. Please note that the amendments to claim 2 reflect amendments made to the sequence identifiers as described below.

Objections to the Specification Under 35 U.S.C. §132

The Examiner has objected to the amendment filed on July 20, 2004, alleging that language such as "consisting essentially of," "variant," "comprising one or more sequences" and "in which one or more amino acid residues are substituted or deleted" introduces new matter into the disclosure. The Examiner stated that Applicants are required to cancel this "new matter" or to point out specifically in the specification or original claims where support for this subject matter can be found.

Applicants respectfully traverse the Examiner's objections. As stated in the Applicants' previous response filed on July 20, 2004, the amendment to the "Summary of the Invention" was made to provide a summary commensurate in scope with the new claims. The M.P.E.P. states that the brief summary of the invention for an application "should be consistent with the subject matter of the claims" (M.P.E.P. at §608.1(d)) and should be modified following

a limitation to the scope of the claims “so as to be in harmony with the claims” (M.P.E.P. at §1302.01). In this regard, the M.P.E.P. at §1302.01 also states that the exact terms used in the claims “need not be used *in haec verba* to satisfy the written description requirement of the first paragraph of 35 USC 112.” In fact, as discussed in the M.P.E.P. §1302.01, the Patent Rules merely require “*substantial* correspondence between the language of the claims and the language of the specification” [emphasis in original].

Applicants assert that the terms “consisting essentially of,” “variant,” “comprising one or more sequences” and “in which one or more amino acid residues are substituted or deleted” correspond substantially with the language used in the specification as filed. For example, the term “consisting essentially of” is an acceptable transitional phrase, the use of which is clearly described in the M.P.E.P. (see §2111.03). The use of this term in the claims as a transitional phrase to define the claimed antagonists corresponds substantially with the various descriptions provided in the instant application for the antagonists of the invention. Support for the term “variant” can be found, for example, at page 13, lines 20 and 28; at page 14, line 1, and at page 15, line 1 of the instant specification. Support for the phrase “comprising one or more sequence” can be found, for example, at page 4, lines 29 to 30 of the specification, wherein the antagonist of the invention is described as comprising “amino acid sequences derived from the prostaglandin F_{2α} receptor” [emphasis added]. Finally, support for the phrase “in which one or more amino acid residues are substituted or deleted” can be found, for example, at page 15, line 1 to page 16, line 9, and in Table 1, at page 14 of the specification, where variants of the peptide PCP-8 that incorporate L- to D- amino acid changes, deletions and substitutions are described. Applicants, therefore, maintain that there is “substantial correspondence” between the language of the claims and that of the instant specification.

For the reasons outlined above, Applicants assert that the claim amendments filed with the Applicants’ previous correspondence of July 20, 2004 are fully supported by the application as filed and consequently, the amendments made to the summary of the invention to reflect these claim amendments are allowable and do not introduce new matter into the disclosure. Accordingly, Applicants respectfully request the reconsideration and withdrawal of the 35 USC §132 rejection on this ground and also request that the Examiner reserve further

commentary in respect of any consequential amendments to the Summary of the Invention until such time as all outstanding matters with regard to the claims have been prosecuted on the merits.

35 U.S.C. §112, first paragraph – New Matter Rejections

The Examiner has rejected claims 1-5 and 10 as failing to comply with the written description requirement. The Examiner alleged that the phrase “consisting essentially of” recited in claim 1, and the phrases “consisting essentially of,” “variant” and “in which one or more amino acid residues are substituted or deleted” recited in claim 2, can not be found in the specification or claims as originally filed. The Examiner has stated that Applicants are required to amend the claims to remove these limitations, or to point out exactly where in the specification support for these limitations can be found. The Examiner has also objected to claims 3-4 and 10 as they depend from claim 1.

For the reasons set forth above, Applicants assert that the language “consisting essentially of,” “variant” and “in which one or more amino acid residues are substituted or deleted” in the claims corresponds substantially with the language of the specification and that the amendments to claims 1-5 and 10 made in the Applicants’ previous correspondence of July 20, 2004, therefore, do not introduce new matter into the disclosure. In order to expedite prosecution of the instant application, however, Applicants have amended claim 1 to replace “consisting essentially of” with “consisting of.” Applicants assert that claims 1-5 and 10 comply with the written description requirement of 35 USC §112, first paragraph and, therefore, respectfully request reconsideration and withdrawal of this rejection.

35 U.S.C. §112, second paragraph – Indefiniteness Rejections

The Examiner has rejected claim 3 as being indefinite. The Examiner acknowledged that Applicants used the language previously suggested by the Examiner; however, the Examiner now alleges that the wording “reduce the occurrence of premature delivery of fetus” is confusing. The Examiner has stated that his concern with respect to the clarity of claim 3, currently on file, is that the wording implies that “a female is regularly

delivering premature fetuses.” The Examiner has suggested that it may be clearer to recite, for example, “reducing the chance of premature delivery of a fetus” or “reducing the occurrence of premature delivery of fetuses in the female population.”

Applicants respectfully traverse the Examiner’s indefiniteness rejection. M.P.E.P. §2173.02 clearly states that “the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available,” and that the definiteness of claim language must be analyzed in light of “[t]he claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.” Applicants submit that a worker skilled in the art would readily appreciate that a female does not, in fact, regularly deliver premature fetuses. Accordingly, a skilled worker would not regard the language of claim 3, currently on file, as indefinite.

However, in order to expedite prosecution of the instant application, Applicants have amended the preamble of claim 3 to recite “A method for decreasing the likelihood of premature delivery of a fetus” as suggested by the Examiner in the Office Action dated April 9, 2003. Support for this amendment can be found throughout the application as filed, specifically, page 5, lns. 24-33. Applicants submit that claim 3 complies with the requirements of 35 U.S.C. §112, second paragraph and, therefore, respectfully request reconsideration and withdrawal of this rejection.

35 U.S.C. §102(b) – Anticipation Rejections

The Examiner has reinstated his rejection of claims 1 and 5 as being anticipated by Abramovitz *et al.* Claim 1 recites a PGF2 receptor antagonist consisting essentially of SEQ ID NO:1 or SEQ ID NOs: 4-11 and the Examiner has stated that, because the phrase “consisting essentially of” has not been defined in the specification, he is interpreting this phrase as “comprising.” The Examiner alleged that claim 1 reads on the full-length receptor and is, therefore, regarded as being anticipated by Abramovitz *et al.*

Applicants respectfully traverse the Examiner’s objection. As referred to in Applicants’ previous correspondence of January 30, 2004, the M.P.E.P. §2103 states that in

order to anticipate a claim, a reference must teach each and every element of the claim. Claim 1, currently on file, is directed to a prostaglandin F2 receptor antagonist consisting essentially of an amino acid sequence derived from the second extracellular loop of a prostaglandin F2 receptor comprising one or more of a specific group of sequences. Claim 5 is directed to a pharmaceutical composition comprising the antagonist of claim 1. Most of the specific sequences recited in claim 1 comprise D-amino acids, *i.e.* non-natural amino acids that would not be present in the naturally occurring receptor. Such sequences thus cannot be anticipated by the disclosure of the sequence of the full-length naturally occurring receptor (*i.e.* a sequence comprising all L-amino acids).

With regard to the Examiner's assertion that the full-length receptor disclosed by Abramovitz *et al.* would act as an antagonist, Applicants respectfully disagree. Figure 3A and 3B of Abramovitz *et al.* referred to by the Examiner show the results of electrophysiological assays that demonstrate the activity of full-length FP receptors that have been expressed in *Xenopus* oocytes and incorporated into the membrane of the cells following injection with a vector comprising DNA encoding the receptor. Abramovitz *et al.*, therefore, reports that it is possible to produce an active receptor protein incorporated into a cell membrane by expressing the receptor protein within a cell. As discussed in Applicants' previous correspondence of January 30, 2004, it is well known in the art that membrane proteins (such as receptors), when taken out of the membrane environment, are unable to adopt their active tertiary structure. One skilled in the art, therefore, would not have a reasonable expectation that the full-length FP receptor protein disclosed by Abramovitz *et al.*, if injected into a cell, would be active and able to function as an antagonist of the endogenous PGF2 receptor as alleged by the Examiner.

However, in order to expedite prosecution of the instant application, Applicants have amended claim 1 to replace the phrase "consisting essentially of" with "consisting of." Applicants submit claims 1 and 5 are not anticipated by Abramovitz *et al.* and, therefore, respectfully request reconsideration and withdrawal of the 35 USC §102(b) rejection to claims 1 and 5 on this ground.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

In the event that the Examiner is of the opinion that further discussion of the application would be helpful, the Examiner is hereby respectfully requested to telephone applicants' undersigned representative at (212) 415-8517 and is assured of full cooperation in an effort to advance the prosecution of the instant application and claims to allowance.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 4591-4000. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 4591-4000. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,

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